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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,905	10/01/2001	Shiken Sha	0230-0169P	5513

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EXAMINER

KEMMERER, ELIZABETH

ART UNIT PAPER NUMBER

1646

DATE MAILED: 03/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/937,905

Applicant(s)

SHA ET AL.

Examiner

Elizabeth C. Kemmerer, Ph.D.

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2004.
2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5,6,9,11,12,18-21,24 and 29-33 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1,2,5,6,9,11,12,18-21,24 and 29-33 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

DETAILED ACTION

Status of Application, Amendments, And/Or Claims

The amendment filed 15 December 2004 has been entered in full. Claims 3, 4, 7, 8, 10, 13-17, 22, 23, and 25-28 are canceled. Claims 1, 2, 5, 6, 9, 11, 12, 18-21, 24, and 29-33 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

The objection to claims 5, 6, 11, 12, 21, and 24 for informalities as set forth at p. 3 of the previous Office Action (mailed 16 June 2004) is *withdrawn* in view of the amended claims (submitted in the reply received 15 December 2004).

The rejection of claims 1, 2, 6, 9, 12, 19, 20, and 21 under 35 U.S.C. § 112, second paragraph, as set forth at pp. 4-5 of the previous Office Action (mailed 16 June 2004) is *withdrawn in part* in view of the amended claims (submitted in the reply received 15 December 2004). Please see section on 35 U.S.C. § 112, second paragraph, below, for maintained portions of the rejection.

The rejection of claims 1, 2, 5, 6, 9, 11, 12 and 21 under 35 U.S.C. § 101 regarding non-statutory subject matter as set forth at p. 5 of the previous Office Action (mailed 16 June 2004) is *withdrawn* in view of the amended claims (submitted in the reply received 15 December 2004).

The rejection of claims 1, 2, 5, 6, 9, 11, 12, 18-21, and 24 under 35 U.S.C. § 112, first paragraph, regarding written description, as set forth at pp. 8-10 of the previous Office Action (mailed 16 June 2004) is *withdrawn* in view of the amended claims (submitted in the reply received 15 December 2004).

35 U.S.C. § 112, Second Paragraph

Claims 18-21 and 24 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 18, 19, and 24 recite the limitation "DNA fragment according to claim 1." There is insufficient antecedent basis for this limitation in the claim due to the amendment to claim 1 deleting the word "fragment."

Claim 20 still recites the phrase "such as" in the third line of the claim. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions

of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 20 recites the broad recitation "substance," and the claim also recites "monoclonal antibody" which is the narrower statement of the range/limitation.

Claim 21 remains confusing in that the method steps are unclear. What is the method screening for? What compounds are being used in the method?

Applicant's arguments (pp. 10-11, reply received 15 December 2004) have been fully considered but are not found to be persuasive for the following reasons. Applicant argues that claim 20 has been amended to remove "such as." this is not found to be persuasive because only one of the two recitations of "such as" have been deleted. Applicant argues that claim 21 has been amended to be in more proper format. This is not found to be persuasive because it is still unclear to the examiner what the method steps are, what activity is being measured, what compound is the constant against which other compounds are screened, and what types of compounds are being screened.

35 U.S.C. §§ 101 and 112, First Paragraph

Claims 1, 2, 5, 6, 9, 11, 12, 18-21, 24, and 29-33 are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a credible, specific, and substantial asserted utility or a well established utility.

Claims 1, 2, 5, 6, 9, 11, 12, 18-21, 24, and 29-33 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported

by either a credible, specific, and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The bases for these rejections can be found at pp. 5-6 of the previous Office Action (mailed 16 June 2004).

Applicant's arguments (pp. 12-14, reply received 15 December 2004) have been fully considered but are not found to be persuasive for the following reasons. Applicant relies upon an English abstract of JP-9-266591 and Aoki et al. (2000, Leukocyte Biology 68:757) as supporting the utility of the claimed polypeptides. Specifically, the documents are characterizing as showing that the polypeptide of the instant invention has the feature of binding to G-CSF inducing antibodies or antibody fragments. This has been fully considered but does not necessitate withdrawal of the rejection. Whether or not the claimed polypeptides bind the antibody is not the issue. The issue is whether or not the specification asserts a credible, specific and substantial utility for the claimed polypeptides. An assertion that the claimed polypeptides can be used to bind the antibodies is not substantial, since it is only for further research regarding the function of the claimed polypeptides in the cell with respect to G-CSF induction.

Based on the binding activity of the claimed polypeptides for the antibody, Applicant argues that the claimed polypeptide may also act at the entry point of induction and stimulation of G-CSF, and that the claimed polypeptide may be a receptor that acts as a G-CSF inducer. Applicant argues that the claimed polypeptide can be used to screen for a substance that can induce G-CSF or other substances, or as a

pharmaceutical agent. This has been fully considered but is not found to be persuasive as it is unsupported conjecture. While the asserted utility is credible and specific, it is not substantial. Significant further research would be required of the skilled artisan to determine what the claimed polypeptides actually do. Several scenarios can be envisioned. The claimed polypeptide could indeed be a receptor. It could also be a G-CSF inhibitor that is neutralized by the antibody, resulting in G-CSF induction. One skilled in the art could not determine the function of the claimed polypeptide without resorting to further research. Since the asserted utility is not in currently available form, it is not substantial.

The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sup. Ct, 1966). The court found that an invention must have either an immediately obvious or fully disclosed "real world" utility. The court held that:

"The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion."

Conclusion

It is noted that an interview was requested on the last page of the amendment. After reviewing the instant Office Action, Applicant may contact the examiner to arrange for such.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D. whose telephone number is (571) 272-0874. The examiner can normally be reached on Monday through Thursday, 7:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (571) 272-0829. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ECK

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER